April 19, 2013 Draft Secure Medicine Return Rule & Regulation: Summary of Changes to March 12, 2013 Draft

Subcommittee Requested Changes:

1. Section 1: added Findings language.
2. Section 5: added definition of "pharmacy" and "retail pharmacy".
3. Section 6: added requirement that producers notify potential collectors of opportunity to voluntarily participate; clarified that producers are responsible for costs as defined under Sections 11 and 18 (6.E.6.).
4. Section 7: added requirement that plans list potential collectors that were contacted and collectors that offered to participate (7.B.).
5. Section 8: added language on other collectors that may be included by producers (8.A., 8. D.); revised provisions for service convenience goal (8.E); added subsection on periodic collection events with voluntary participation of law enforcement (8.G.).
6. Section 9: added requirement that plan website(s) include current locations of drop-off sites (9.A.3.); added language related to clear instructions for residents, including for limited English proficiency populations (9.A.3.).
7. Section 10: modified disposal facility requirements.
8. Section 11: modified provisions on purchase of secure drop boxes (11.B.).
9. Section 13: changed deadline for provision of producers list by drug wholesalers.
10. Section 14: added provisions on process if a revised stewardship plan is rejected.
11. Section 15: revised notification requirements for changes to stewardship plans.
12. Section 18: added language on fee for review of an updated plan (18.A.4.); clarified language on fees recovering actual costs (18.D.); reorganized the section.

Technical Changes from Staff:

1. Section 5: language corrections to the following definitions: "covered drug", "covered entities", "independent product stewardship plan", "manufacturer", "prescription drug", "producer", and "standard product stewardship plan".
2. Section 6: language clarifications and reorganization of the section; relocated language from Section 14 that producers must submit an updated plan at least every four years; added language clarifying when independent plans may be submitted after initial start-up.
3. Section 7: adjusted requirements for collection system description to reflect modifications in Section 8 (7.B.), added requirement that plans include copies of instructions and signage (7.H.); language clarifications.
4. Section 8: revisions to language on equitable opportunities (8.B.); language clarifications and section reorganization.
5. Section 9: moved language in 9.F. to Findings (Sec.1); language clarifications and section reorganization.
6. Section 11: adjusted language in 11.A. to reflect collection system requirements in Sec. 8; language clarifications.
7. Section 12: adjusted language in 12.A.3. to reflect collection system requirements in Sec. 8; language clarifications in 12.A.
8. Section 14: relocated language that producers must resubmit an updated plan at least every four years to Sec. 6.E.5.; section reorganization.
9. Section 16: language corrections.
10. Section 18: language clarifications and section reorganization.
11. Changed all placeholder fixed dates to time frames relative to adoption of the rule.
12. Corrections of discovered punctuation and other typographical errors throughout.

Date Created:	
Drafted by:	
Attachments:	

..Title

A RULE AND REGULATION relating to providing safe collection and disposal of unwanted drugs from residential sources through producer provided and funded product stewardship plans, and adding a new chapter to BOH Title 3; enacted pursuant to RCW 70.05.060, including the latest amendments or revisions thereto.

..Body

BE IT ADOPTED BY THE KING COUNTY BOARD OF HEALTH:

SECTION 1. **Findings.**

A. Residents of King County benefit from the authorized use of prescription and non-prescription (over-the-counter) medicines; however abuse, fatal overdoses, and poisonings from prescription and non-prescription medicines used in the home have emerged as an epidemic in recent years.

B. More people die from prescription medicines than from all illegal drugs combined. Drug overdoses in King County have surpassed car crashes as a leading cause of preventable deaths, with the majority of overdoses involving prescription opiates.

C. Prescription and non-prescription medicines used in the home are the leading cause of poisonings reported to the Washington Poison Center, and preventable poisonings from medicines have been rising rapidly, especially among children and seniors.

D. Unused, expired, and leftover drugs that accumulate in homes increase risks of drug abuse, overdoses, and preventable poisonings. A system for the proper disposal of unneeded drugs is an element of a comprehensive strategy to prevent prescription drug abuse.

E. Flushing medicines down toilets and sinks is an inappropriate disposal practice because wastewater treatment facilities cannot effectively remove or degrade all pharmaceutical compounds. Trash disposal of medicines is an undesirable disposal option because trash cans are not secure and mixed pharmaceutical wastes are household hazardous wastes that should not be disposed of in the solid waste stream.

F. Medicine take-back programs provide secure collection and environmentally sound destruction of unwanted medicines to protect public health.

G. Voluntary medicine take-back programs in the county are insufficient to protect the public, so local action is warranted to reduce risks of abuse, overdoses, and poisoning.

H. The Board of Health finds it in the interest of public health to establish a county-wide secure medicine return program providing equitable access for all of the county's residents that is financed and operated by drug producers selling medicines in or into King County for residential use.

I. The Board of Health approved the Local Hazardous Waste Management Program's plan, on April 15, 2010, which states support for product stewardship approaches for waste pharmaceuticals from residential sources. The plan states that product stewardship provides a means "to shift from a system focused on government-funded and ratepayer-financed waste disposal and diversion, to one that relies on

producer responsibility in order to reduce public costs, increase accessibility to services, attain higher environmental benefits, and drive improvements in product design that promotes environmental sustainability."

J. Drug producers are well-positioned to efficiently develop and operate the medicine take-back system, working with other stakeholders such as pharmacies and law enforcement, within standards prescribed by the Board to ensure safety and security of the system, and in compliance with pertinent federal and state laws, regulations, and guidelines.

K. The Board of Health encourages pharmacies, health care providers, health professionals, government agencies responsible for solid waste management, wastewater treatment, and health and community organizations in the county to inform residents through all their standard communication methods about safe storage of medicines and the use of collection services for unwanted medicines provided through the drug producers' stewardship program.

SECTION 2. Sections 1, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, and 18 of this rule should constitute a new chapter on secure medicine return in BOH Title 3.

NEW SECTION. SECTION 3. **Citation.** This chapter may be cited and referred to, and shall be known as, the "King County Board of Health Secure Medicine Return Regulations."

NEW SECTION. SECTION 4. **Purpose and scope of chapter.**

A. This chapter is enacted as an exercise of the board of health powers of King County to protect and preserve the public health, safety, and welfare. Its provisions shall be liberally construed for the accomplishment of these purposes. This chapter governs

the protection of human health and safety against the improper handling and disposal of leftover or expired medicines.

B. It is the specific intent of this chapter to place the obligation of complying with its requirements upon drug producers, stewardship organizations and other persons designated by this chapter within its scope, and any provision of or term used in this chapter is not intended to impose any duty whatsoever upon King County or any of its officers or employees, for whom the implementation or enforcement of this chapter shall be discretionary and not mandatory.

NEW SECTION. SECTION 5. **Definitions.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

A. "Collector" means a person that gathers unwanted covered drugs from covered entities for the purpose of collection, transportation and disposal.

B. 1. "Covered drug" includes all prescription and nonprescription drugs sold in any form and used by covered entities, including brand name and generic drugs.

2."Covered drug" does not include:

a. Vitamins or supplements;

b. Herbal-based remedies and homeopathic drugs, products, or remedies;

c. Cosmetics, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and nonprescription drugs under the federal food, drug, and cosmetic act;

d. Drugs for which producers provide a pharmaceutical product stewardship or take-back program as part of a federal food and drug administration managed risk evaluation and mitigation strategy (21 U.S.C. Sec. 355-1);

e. Drugs that are biological products as defined by 21 C.F.R. 600.3(h) as it exists on the effective date of this chapter if the producer already provides a pharmaceutical product stewardship or take-back program;

f. Medical devices, their component parts or accessories, or a covered drug contained in or on medical devices or their component parts or accessories; and

g. Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms.

C. “Covered entities” means residents of King County, including individuals living in single and multiple family residences and other residential settings including other non-business sources as identified by the director. “Covered entities” does not include business generators of pharmaceutical waste, such as hospitals, clinics, doctor’s offices, veterinarian clinics, pharmacies, or airport security and law enforcement drug seizures.

D. "Director" means the director of the Seattle-King County Department of Public Health or the director's duly authorized representative.

E. "Drug wholesaler" means a corporation, individual, or other entity which buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

F. "Drugs" means:

1. Articles recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias;

2. Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

3. Substances, other than food, intended to affect the structure or any function of the body of humans or other animals; or

4. Substances intended for use as a component of any substances specified in subsection F.1., F.2. or F.3 of this subsection, but not including medical devices, their component parts or accessories, or a covered drug contained in or on medical devices or their component parts or accessories.

G. "Independent product stewardship plan" or "independent stewardship plan" means a plan other than the standard product stewardship plan for the collection, transportation, and disposal of unwanted covered drugs that may be proposed by a producer or group of producers; and, if approved, is financed, developed and implemented by the participating producer or group of producers, and operated by the participating producer or producers or a stewardship organization.

H. "Local hazardous waste management program" means the King County local hazardous waste management program identified in BOH chapter 2.08.080.

I. "Manufacture" means as defined in RCW 18.64.011(15) the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, prepares, compounds, packages, or labels such substance or device.

J. "Manufacturer" means a person, corporation, or other entity engaged in the manufacture of drugs or devices, as defined in RCW 18.64.011(16).

K. “Mail-back services” means a collection method for the return of unwanted covered drugs from covered entities utilizing prepaid and preaddressed mailing envelopes.

L. "Nonprescription drug" means any drugs that may be lawfully sold without a prescription.

M. "Person" means a firm, sole proprietorship, corporation, limited liability company, general partnership, limited partnership, limited liability partnership, association, cooperative, or other entity of any kind or nature.

N. “Pharmacy” means every place properly licensed by the state of Washington board of pharmacy where the practice of pharmacy is conducted as defined under RCW 18.64.011.

O. "Prescription drug" means any drugs, including controlled substances under chapter 69.50 RCW, that are required by an applicable federal or state law or regulation to be dispensed by prescription only or are restricted to use by practitioners only.

P. "Producer” means a manufacturer who is engaged in the manufacture of a covered drug sold in or into King County, including brand name or generic drugs. "Producer" does not include:

1. A retailer whose store label appears on a covered drug or the drug's packaging if the manufacturer from whom the retailer obtains the drug is identified under section 6.C of this rule; or

2. A pharmacist who compounds a prescribed individual drug product for a consumer; or

3. A wholesaler who is not also a manufacturer.

Q. “Retail pharmacy” means a pharmacy properly licensed by the state of Washington board of pharmacy for retail sale and dispensing of drugs.

R. "Standard product stewardship plan" or "standard stewardship plan" means the plan for the collection, transportation, and disposal of unwanted covered drugs that is financed, developed, implemented and participated in by producers, operated by the participating producers or a stewardship organization, and approved as the standard product stewardship plan.

S. "Stewardship organization" means an organization designated by a producer or group of producers to act as an agent on behalf of each producer to develop and implement and operate the standard product stewardship plan or an independent product stewardship plan.

T. "Unwanted covered drug" means any covered drug no longer wanted by its owner or that has been abandoned, discarded, or is intended to be discarded by its owner.

NEW SECTION. SECTION 6. **Product stewardship plans – Participation.**

A. Each producer shall participate in the standard product stewardship plan approved by the director, except that a producer may individually, or with a group of producers, form and participate in an independent product stewardship plan if approved by the director.

B. The standard product stewardship plan and any independent product stewardship plan shall be approved by the director before collecting unwanted covered

drugs. Once approved, product stewardship plans must have prior written approval of the director for proposed changes as described under Section 15 of this rule.

C. By six months after this rule is adopted, each producer of covered drugs sold in or into King County shall notify the director in writing of the producer's intent to participate in the standard product stewardship plan or to form and participate in an independent product stewardship plan. A retailer whose store label appears on a covered drug or the drug's packaging must notify the director of intent to participate or provide written notification that the manufacturer from whom the retailer obtains the drug has provided its notice of intent to participate.

E. A producer or group of producers participating in the standard product stewardship plan or an independent product stewardship plan shall:

1. By nine months after this rule is adopted, identify in writing to the director a plan operator, including the plan operator's telephone, mailing address and email contact information, who is authorized to be the official point of contact for the product stewardship plan.

2. By nine months after this rule is adopted, notify all retail pharmacies and law enforcement agencies in the county of the opportunity to participate as a drop-off site, provide information about collection policies and procedures, and provide a process for forming an agreement between the plan and interested collectors; and annually thereafter, make the same notification to any non-participating or new retail pharmacies or law enforcement agencies in the county.

3. By one year after this rule is adopted, submit a proposed product stewardship plan as described in section 7 of this rule to the director for review;

4. Within three months after the director's approval of their stewardship plan or no later than eighteen months after this rule is adopted, operate or participate in a product stewardship plan in accordance with this chapter;

5. At least every four years after each plan initiates operations, the standard product stewardship plan and any approved independent product stewardship plan shall submit an updated plan to the director explaining any substantive changes to components of the stewardship plan required in section 7 of this rule, and accompanied by the review fee in accordance with section 18 of this rule. The director shall review updated stewardship plans using the process described in section 14 of this rule; and

6. Producers participating in a stewardship plan shall pay all administrative and operational costs and fees associated with their product stewardship plan as defined under Sections 11 and 18 of this rule.

F. A producer or group of producers participating in the standard product stewardship plan or an independent product stewardship plan may:

1. Enter into contracts and agreements with stewardship organizations, other service providers, or other entities as necessary, useful, or convenient to provide all or portions of their product stewardship plan;

2. Notify the director of any producer selling covered drugs in or into King County that is failing to participate in a product stewardship plan; and

3. Perform any other functions as may be necessary or proper to provide the product stewardship plan and to fulfill any or all of the purposes for which the plan is organized.

F. After the first full year of operation of the approved standard stewardship plan, a producer or group of producers participating in the standard stewardship plan may notify the director in writing of intent to form an independent product stewardship plan, and identify a plan operator, including the plan operator's telephone, mailing address and email contact information, who is authorized to be the official point of contact for the proposed independent stewardship plan. Within three months of such notification, the producer or group of producers may submit a proposed independent product stewardship plan as described under section 7 of this rule to the director for review.

G. Submission dates and deadlines described in this section may be extended to a later date as approved in writing by the director.

H. After presenting official credentials and providing notice of an audit or inspection to determine compliance with this chapter or to investigate a complaint, the director may audit a producer's, group of producers', or stewardship organization's records related to a product stewardship plan or request that the producer, group of producers, or stewardship organization arrange for the director to inspect at reasonable times a product stewardship plan's or a collector's, transporter's, or disposal company's facilities, vehicles, and equipment used in carrying out the stewardship plan.

NEW SECTION. SECTION 7. **Product stewardship plans – Components.** The standard product stewardship plan or any independent product stewardship plan, which must be submitted and reviewed according to section 14 of this rule, shall include the following:

A. Contact information for all drug producers participating in the product stewardship plan;

B. A description of the proposed collection system to provide convenient ongoing collection service to covered entities in compliance with the provisions and requirements in section 8 of this rule, including a list of all collection methods, participating collectors and drop-off locations, and an example of the prepaid, preaddressed mailers to be utilized. The description shall include a list of retail pharmacies and law enforcement agencies contacted by the plan under subsection 6.E.2. of this rule, and a list of all collectors who offered to participate;

C. A description of the handling and disposal system, including identification of and contact information for collectors, transporters, and waste disposal facilities to be used by the product stewardship plan in accordance with sections 8 and 10 and other provisions of this rule;

D. A description of how the stewardship plan will use existing providers of waste pharmaceutical services to the extent possible;

E. A description of the policies and procedures to be followed by persons handling unwanted covered drugs collected pursuant to the product stewardship plan, including a description of how all collectors, transporters and waste disposal facilities utilized will ensure the collected, unwanted covered drugs are safely and securely tracked from collection through final disposal, and how all entities participating in the product stewardship plan will operate under all applicable federal and state laws, rules and guidelines, including those of the United States drug enforcement administration, and how any pharmacy collection site will operate under applicable rules and guidelines of the state of Washington board of pharmacy;

F. A description of how covered drugs will be separated from packaging to the extent possible to reduce transportation and disposal costs, and how drug packaging will be recycled to the extent feasible;

G. A description of how patient information on drug packaging will be kept secure during collection, transportation, and recycling or disposal;

H. A description of the public education effort and promotion strategy required in section 9 of this rule, including a copy of standardized instructions for residents, signage developed for collectors, and required promotional materials; and

I. A proposal on the short term and long term goals of the product stewardship plan for collection amounts, education and promotion.

NEW SECTION. SECTION 8. **Product stewardship plans – Collection of covered drugs.**

A. This chapter does not require any person to serve as a collector in a product stewardship plan. A person may offer to serve as a collector voluntarily, or may agree to serve as a collector in exchange for incentives or payment offered by a producer, group of producers or stewardship organization. Collectors may include law enforcement, pharmacies, mail-back services, or other entities, operating in accordance with state and federal laws and regulations for the handling of covered drugs, including those of the United States drug enforcement administration, and in compliance with this chapter. Any pharmacy collection site shall operate under applicable rules and guidelines of the state of Washington board of pharmacy.

B. The collection system shall be convenient on an ongoing basis to adequately serve the needs of covered entities and shall be designed in consideration of equitable

opportunities for all King County residents for the safe and convenient return of unwanted covered drugs, in accordance with the requirements of this section.

C. The collection system for all unwanted covered drugs shall be safe and secure, including protection of patient information on drug packaging.

D. In establishing and operating a product stewardship plan, a producer, group of producers or stewardship organization shall give preference to having retail pharmacies and law enforcement agencies serve as drop-off sites, and shall include, as collectors, any retail pharmacy or any law enforcement agency willing voluntarily to serve as a drop-off site for unwanted covered drugs and able to meet the requirements of this chapter. A producer or group of producers establishing and operating a product stewardship plan may also accept other collectors willing to serve as a drop-off site for unwanted covered drugs and able to meet the requirements of this chapter. Drop-off sites shall accept covered drugs from covered entities during all hours that the retail pharmacy, law enforcement agency, or other collector is normally open for business with the public. Drop-off sites shall utilize secure drop boxes in compliance with all applicable requirements of the United States drug enforcement administration and the state of Washington board of pharmacy.

E. The service convenience goal for the standard stewardship plan and any independent stewardship plan is a system of drop-off sites distributed to provide reasonably convenient and equitable access for all residents in incorporated and unincorporated areas of the county, to achieve:

1. In every city or town with a pharmacy or law enforcement facility, at least one drop-off site and at least one additional drop-off site for every thirty thousand

residents, geographically distributed to provide reasonably convenient and equitable access throughout the city; and

2. Throughout the county, a geographic distribution of drop-off sites to provide reasonably convenient and equitable access to residents of unincorporated areas of the county.

If the service convenience goal in subsections 1. and 2. cannot be achieved by the standard stewardship plan or any independent stewardship plan due to a lack of drop-off sites at pharmacies, law enforcement agencies, or other qualified collectors in specific areas of the county, then those areas shall be served through periodic collection events or mail-back services, or a combination of these collection methods.

F. Mail-back services shall be made available to differentially-abled and home bound residents upon request through the stewardship plan's toll-free telephone number and web site, and through distribution of prepaid, preaddressed mailers to persons providing services to such residents; and may also be utilized as a collection method according to subsection E.

G. Periodic collection events, if utilized as a collection method according to subsection E., must be arranged with law enforcement personnel through voluntary agreements, and shall be conducted in compliance with U.S. drug enforcement administration protocols, any additional requirements of participating law enforcement agencies, and in compliance with this chapter.

NEW SECTION. SECTION 9. **Product stewardship plans – Promotion.**

A. A producer or group of producers participating in the standard product stewardship plan or an independent product stewardship plan shall:

1. Promote the use of their product stewardship plan so that collection options for covered drugs are widely understood by residents, pharmacists, retailers of covered drugs, and health care practitioners including doctors and other prescribers, and promote the safe storage of covered drugs by residents prior to secure disposal through their stewardship plan;

2. Work with collectors participating in their product stewardship plan to develop clear, standardized instructions for residents on the use of drop boxes. The local hazardous waste management program may provide guidance to producers and collectors on the development of these instructions;

3. Establish a toll-free telephone number and web site where collection options and current locations of drop-off sites will be publicized and prepare educational and outreach materials describing safe storage of medicines and describing where and how to return unwanted covered drugs to the product stewardship plan. These materials must be provided to pharmacies, health care facilities, and other interested parties for dissemination to residents. Plain language and explanatory images should be utilized to make use of medicine collection services readily understandable by all residents, including individuals with limited English proficiency. A producer or group of producers participating in the standard stewardship plan and any independent stewardship plans shall coordinate these promotional activities to ensure that residents can easily identify, understand and access the collection services provided by any stewardship plan;

4. Annually evaluate the effectiveness of its outreach and product stewardship plan activities; and

5. Conduct a survey of residents of King County to determine the percentage of residents that are aware of the product stewardship plan and to what extent residents find the plan convenient after the first full year of operation of the plan, and again after five and nine years of operation. Results of the survey shall be reported to the director and made available to the public on the stewardship plan's website.

B. The local hazardous waste management program shall:

1. Promote the use of product stewardship plans and the plans' toll-free telephone numbers and web sites through their standard educational methods;

2. Provide sample educational materials for use by pharmacies, law enforcement agencies, health care providers and local government agencies in the county;

3. Conduct educational outreach to targeted populations and groups as informed by survey results and other research indicators; and

4. Assume the costs of developing and providing promotional and educational materials under this subsection.

NEW SECTION. SECTION 10. **Product stewardship plans – Disposal of covered drugs.**

A. Covered drugs collected under a product stewardship plan must be disposed of at a properly permitted hazardous waste disposal facility as defined by the United States environmental protection agency under 40 CFR parts 264 and 265.

B. The director may grant approval for a producer or producers participating in the standard stewardship plan or an independent product stewardship plan to dispose of some or all collected covered drugs at a properly permitted large municipal waste combustor, as defined by the United States environmental protection agency under 40

CFR parts 60 and 62, if use of a hazardous waste disposal facility described under subsection A is deemed not feasible for the stewardship plan based on cost, logistics, or other considerations.

C. A producer or producers participating in the standard stewardship plan or an independent product stewardship plan may petition the director for approval to use final disposal technologies that provide superior environmental and human health protection than provided by the disposal technologies in subsections A. and B. of this section, or equivalent protection at lesser cost. The proposed technology must provide equivalent or superior protection in each of the following areas:

1. Monitoring of any emissions or waste;

2. Worker health and safety;

3. Air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and

4. Overall impact to the environment and human health.

NEW SECTION. SECTION 11. **Product stewardship plans – Administrative and operational costs and fees.**

A. A producer or group of producers participating in the standard product stewardship plan or an independent product stewardship plan shall pay all administrative and operational costs related to their product stewardship plan, except as provided under this section. Administrative and operational costs related to the product stewardship plan include the following:

1. Collection and transportation supplies for each drop-off site;

2. Costs of pre-paid, pre-addressed mailers provided to differentially-abled and home bound residents, and to specific areas of the county if utilized;

3. Costs of operating periodic collection events if utilized, including costs of law enforcement staff time if necessary;

4. Transportation of all collected pharmaceuticals to final disposal, including costs of law enforcement escort if necessary;

5. Environmentally sound disposal of all collected pharmaceuticals under section 10 of this rule; and

6. Program promotion under section 9 of this rule.

B. The local hazardous waste management program shall purchase secure drop boxes for retail pharmacies and law enforcement agencies willing to volunteer as drop-off sites for the standard stewardship plan.

C. No person or producer may impose a visible fee on consumers when covered drugs are purchased or returned.

D. Producers are not required to pay for costs of staff time at drop-off sites provided by collectors volunteering for a product stewardship plan.

NEW SECTION. SECTION 12. **Product stewardship plans – Reporting requirements.**

A. Within six months after the end of the first twelve month period of operation, and annually thereafter, the plan operator of the standard product stewardship plan and of any independent product stewardship plan shall submit a report to the director on behalf of participating producers describing their plan's activities during the previous reporting period to comply with this chapter. The report must include the following:

1. A list of producers participating in the product stewardship plan;

2. The amount, by weight, of unwanted covered drugs collected, including the amount by weight from each collection method used;

3. A list of drop-off locations, the number of mailers provided for differentially-abled and home bound residents, locations where mailers were provided, if applicable, dates and locations of collection events held, if applicable, transporters used, and the disposal facility or facilities used;

4. Whether any safety or security problems occurred during collection, transportation, or disposal of unwanted covered drugs during the reporting period and, if so, what changes have or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security in the future;

5. A description of the public education, outreach, and evaluation activities implemented during the reporting period;

6. A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used;

7. A summary of the product stewardship plan goals, the degree of success in meeting those goals in the past year, and if any goals have not been met, what effort will be made to achieve such goals in the next year; and

8. The total expenditure of the stewardship plan during the reporting period.

B. The director shall make reports submitted under this section available to the public.

C. For the purposes of this section, "reporting period" means the period commencing January 1st and ending December 31st of the same calendar year, unless otherwise specified to the plan operator by the director.

NEW SECTION. SECTION 13. **Product stewardship plans – Lists of producers of covered drugs.** Beginning sixty days after this rule is adopted, each drug wholesaler that sells any covered drug in or into the county must provide a list of producers of covered drugs to the local hazardous waste management program in a form agreed upon with the director. Wholesalers must update the list by January 15th of each year.

NEW SECTION. SECTION 14. **Product stewardship plans – Review of proposed plans.**

A. By one year after this rule is adopted, a producer, group of producers, or stewardship organization participating in the standard stewardship plan or any independent stewardship plan shall submit their proposed product stewardship plan to the director for review, accompanied by the plan review fee in accordance with section 18 of this rule.

B. The director shall review the proposed product stewardship plan and determine whether the proposed plan meets the requirements of section 7 and other applicable sections of this rule. In reviewing a proposed product stewardship plan, the director shall provide opportunity for written public comment and consider any comments received.

C. After the review under subsection B. of this section and within ninety days after receipt of the proposed product stewardship plan, the director shall either approve or

reject the proposed product stewardship plan and, if rejected, provide reasons for rejection.

D. If the proposed product stewardship plan is rejected, a producer or group of producers must submit a revised product stewardship plan to the director within sixty days after receiving notice of the rejection. The director shall review and approve or reject a revised product stewardship plan as under subsections B. and C.

E. If the director rejects a revised product stewardship plan, or any subsequently revised plan, the producer or group of producers shall be deemed out of compliance with this chapter and is subject to the enforcement provisions contained in this chapter.

1. If the revised standard stewardship plan is rejected, the director may, in the director's sole discretion, require the submission of a further revised standard stewardship plan or develop and impose changes to some or all components of the rejected plan to constitute an approved standard stewardship plan. If the director imposes some or all of the approved plan, the producers participating in the approved standard stewardship plan in accordance with this chapter shall not be considered out of compliance with this chapter.

2. If a revised independent stewardship plan is rejected, the producer or group of producers submitting the independent stewardship plan shall participate in the standard stewardship plan and shall not be eligible to propose an independent stewardship plan for six months after such rejection. Any producers whose revised independent stewardship plan is rejected shall not be considered out of compliance with this chapter if they participate in and comply with the standard stewardship plan.

H. In approving a proposed product stewardship plan, the director may exercise reasonable discretion to waive strict compliance with the requirements of this chapter that are applicable to producers in order to achieve the objectives of this chapter.

NEW SECTION. SECTION 15. **Product stewardship plans - Prior approval for change.**

A. Proposed changes to an approved product stewardship plan that substantively alter plan operations, including, but not limited to, changes to participating manufacturers, collection methods, achievement of the service convenience goal, procedures for handling covered drugs, education and promotion methods, or disposal facilities must have prior written approval of the director.

B. A producer or producers participating in the standard stewardship plan or any independent stewardship plan shall submit to the director any proposed change to a product stewardship plan as described under subsection A. in writing and accompanied by the review fee in accordance with section 18 of this rule.

C. A producer or producers participating in the standard stewardship plan or any independent stewardship plan shall inform the director in writing of proposed changes in policies or procedures for collection, handling, or disposal of covered drugs at least thirty days before the changes occur. All other proposed changes shall be submitted in writing at least fifteen days before the changes occur.

NEW SECTION. SECTION 16. **Product stewardship plans – Enforcement – Penalty.**

A. The director shall send a written warning and a copy of this chapter and any rules adopted to implement this chapter to a producer who is not participating in the

standard product stewardship plan or an independent product stewardship plan as required under this chapter. The warning shall state that participation in a plan is required and warn of penalties for noncompliance.

B. A producer not participating in the standard product stewardship plan or an independent product stewardship plan and whose covered drug continues to be sold in or into the county sixty days after receiving a written warning from the director may be assessed a penalty pursuant to subsections D. and E. of this section.

C. If the director determines that a product stewardship plan is not in compliance with this chapter or its plan approved pursuant to section 14 of this chapter, the director may send the producer or group of producers participating in the plan a written warning stating the plan is not in compliance, providing notice of the compliance requirements and warning of penalties for noncompliance. The producer or group of producers has thirty days after receipt of the notice to achieve compliance. If the product stewardship plan is not in compliance after thirty days, the director may assess a penalty pursuant to subsections D. and E. of this section. This subsection does not preclude the director from suspending an approved plan if a violation of this chapter or an approved plan creates a condition that, in the director's judgment, constitutes an immediate hazard.

D. A violation of this chapter is subject to a civil penalty of up to $2,000 and may be assessed against a producer or group of producers. Each day upon which a violation occurs or is permitted to continue constitutes a separate violation. In determining the appropriate penalty, the director shall consider the extent of harm caused by the violation, the nature and persistence of the violation, the frequency of past violations, any action

taken to mitigate the violation, the financial burden to the violator, and the size of the violator's business.

E. The director may utilize the provisions of BOH chapter 1.08 to assess civil penalties provided in this section. A producer or group of producers may appeal assessments imposed under this section as provided in BOH chapter 1.08. In addition to or as an alternative to utilizing the procedures set forth in BOH chapter 1.08, the director may assess or recover penalties accruing under this section by legal action filed in King County superior court.

NEW SECTION. SECTION 17. **Product stewardship plans – Administrative rules, performance standards, and report.**

A. The director may adopt rules necessary to implement, administer, and enforce this chapter.

B. The director may work with the plan operator to define goals for collection amounts, education, and promotion for a product stewardship plan.

C. The director shall report annually to the King County board of health concerning the status of the standard and independent product stewardship plans and recommendations for changes to this chapter.

NEW SECTION. SECTION 18. **Plan review and annual operating fees.**

A. A producer or group of producers participating in the standard product stewardship plan or an independent product stewardship plan shall pay to the director plan review fees to be established under subsection D of this section for:

1. Review of a proposed product stewardship plan;

2. Resubmittal of a proposed stewardship plan;

3. Review of changes to an approved stewardship plan; or

4. Submittal of an updated stewardship plan at least every four years under subsection 6.E.5. of this rule.

B. In addition to plan review fees, a producer or group of producers participating in the standard product stewardship plan or an independent product stewardship plan shall pay to the director annual operating fees to be established under subsection D. of this section.

C. A plan operator or a stewardship organization may remit the fee on behalf of participating producers.

D. As soon as practicable, the director shall propose to the board of health a schedule of fees to be charged to a producer or producers to cover costs of administering and enforcing this chapter. Fees shall be calculated to recover actual costs.

SECTION 19. **Severability.** If any provision of this rule or its application to any person or circumstance is held invalid, the remainder of the rule or the application of the provision to other persons or circumstances is not affected.